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NICE advice

MiraQ cardiac TTFM with high-frequency probe for assessing graft flow during coronary artery bypass graft surgery

Medtech innovation briefing
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Overview

NICE has developed a medtech innovation briefing (MIB) on MiraQ cardiac TTFM with high-frequency probe for assessing graft flow during coronary artery bypass graft surgery.

The information provided includes a description of the technology, how it's used and its potential role in the treatment pathway. A MIB also includes a review of relevant published evidence and the likely costs of using the technologies, but they are not NICE guidance and do not make any recommendations on the value of using the technologies.

Summary

- The **technology** described in this briefing is the MiraQ cardiac transit time flowmetry (TTFM) and high-frequency ultrasound (HFUS) system. It is used for intraoperative quality assessment of graft blood flow during coronary artery bypass graft (CABG) surgery for people with coronary heart disease.
- The **innovative aspect** is the L15 HFUS imaging probe that is designed to improve near-field imaging and is applied directly to the cardiac tissue.
- The intended **place in therapy** would be as an alternative to clinical assessment in people undergoing CABG surgery.
- The **main points from the evidence** summarised in this briefing are from 4 studies (1 multicentre observational registry, 1 secondary analysis, 1 prospective study and 1 retrospective observational study) including a total of 1,134 people undergoing CABG surgery. They show that MiraQ cardiac with TTFM and HFUS may improve the quality and efficacy of the CABG procedure.
- **Key uncertainties** around the evidence or technology are that there is limited UK NHS evidence and none of the studies included a comparator.
- **Experts advised** that the main benefits of the technology are providing surgeons with detailed objective information about the graft condition and graft flow, and helping them detect the position of deep lying arteries during the procedure. These may reduce long-term graft failure, and the risk of bleeding and intraoperative complications.
- **Safety issues** identified with the MiraQ system are that there have been incidences when flow measurement channels incorrectly indicated that the flow is too high or too low, which could cause surgeons to make unnecessary changes and potentially lead to graft failure. The instructions for use have been updated to address the problem.
- The **cost** of the MiraQ cardiac TTFM and HFUS system is £81,550 per unit, the L15 imaging probe is £8,365 and the TTFM probe is £1,720 (excluding VAT). Standard care is clinical assessment of graft flow using a variety of techniques, which are selected based on surgeon preference.

The technology

MiraQ cardiac (Medistim) combines transit time flow measurement (TTFM) and high-frequency ultrasound (HFUS) modalities within a single system. Surgical findings can be documented through flow tracing and images provided by the system. It is intended for intraoperative quality assessment of graft blood flow during coronary artery bypass graft (CABG) surgery. The system consists of 2 probes. The L15 HFUS imaging probe has a frequency range of 11 MHz to 18 MHz and provides high-resolution images that allow the surgeon to assess morphology, including the cannulation or clamping site of the aorta, and to evaluate the completed bypass anastomosis. The TTFM probe uses transit time technology to accurately measure blood flow intraoperatively. It measures 3 parameters of transit time flow (mean blood flow in ml per minute, pulsatility index and diastolic filling percentage) to assess graft blood flow and check graft patency. A microcomputer with a touchscreen mounted on a moveable trolley is used to control the probes and store their outputs.

There is another version available, the MiraQ TTFM system, that does not include HFUS. This version has been evaluated separately in NICE's medical technologies guidance on MiraQ for assessing graft flow during CABG surgery and is not part of this briefing.

Innovations

The company claims that the L15 imaging probe is designed to improve near-field imaging using HFUS and is applied directly to the cardiac tissue. The company also claims that intraoperative quality assessment and surgical guidance using HFUS is more likely to lead to a positive outcome and decrease the chance for additional surgical reinterventions.

Current care pathway

Coronary artery disease is a common cause of symptoms, disability and death. It is caused by atherosclerosis, which leads to stenosis or occlusion of the coronary arteries. NICE's guideline on stable angina: management recommends that revascularisation of the blocked coronary arteries using CABG or percutaneous coronary interventions should be considered in people whose symptoms are not satisfactorily controlled by medical treatment.

CABG surgery aims to bypass narrowed or blocked segments of the coronary arteries

using grafts. Grafts are usually constructed from lengths of the patient's own long saphenous vein or internal mammary artery, although other blood vessels are also used.

Cardiac surgeons use a variety of techniques to avoid technical problems during CABG surgery, but assessment of graft flow is usually subjective. Techniques used vary according to the graft used, the surgical technique, and the surgeon's individual preference. They include the surgeon assessing resistance and perfusion beyond a graft by flushing fluid through it before restoring flow, and observing and palpating grafts for pulsation when blood flow has been re-established.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on stable angina: management
- NICE's guideline on acute coronary syndromes
- European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) guidelines on myocardial revascularization.

Population, setting and intended user

The MiraQ cardiac TTFM and HFUS system is intended for use in people with coronary artery disease undergoing CABG surgery.

The technology is used by cardiovascular surgeons, with nurses operating the system. It is used in tertiary care during cardiac surgery.

The company states that both the surgeon and the operator of the MiraQ cardiac system need to be trained in using the system. The training is provided by the company and is included in the cost of the device.

Costs

Technology costs

- MiraQ cardiac TTFM and HFUS system: £81,550
- unit cost L15 imaging probe: £8,365

- unit cost TTFM probe: £1,720
- annual maintenance costs (based on 10-year lifetime): £2,086.

Costs of standard care

Standard care is clinical assessment of graft flow using a variety of techniques, which are selected based on surgeon preference. These usually involve minimal or no extra cost.

Resource consequences

The company states that MiraQ cardiac with TTFM and HFUS is used in 6 NHS trusts.

The company claims that using the MiraQ cardiac TTFM and HFUS system reduces postoperative deaths and re-hospitalisations when compared with both CABG surgery alone and CABG surgery with the MiraQ TTFM system.

The company states that there are no practical difficulties or changes in facilities and infrastructure associated with adopting MiraQ. It is a standalone system that only needs an electrical output socket.

Regulatory information

MiraQ cardiac transit time flow measurement and high-frequency ultrasound system is a CE-marked class IIa medical device, and the probes used with the MiraQ system are CE-marked class III.

There is a field safety notice on Medistim ASA: VeriQ, MiraQ. Medistim is aware of incidences when flow measurement channels on Medistim devices have been operating with a significant zero-point offset value. The result is that flow measurements recorded with these channels will indicate that the flow is too high or too low. This might result in worse patient outcomes. Exploration of the issue has shown that this malfunction was caused by electrostatic discharge (ESD) damaging a component in the measurement chain on the Medistim systems, causing an offset from zero. Medistim tests the ESD resistance during compliance testing to ensure the system meets electromedical safety standard requirements. However, the incidences noted above have shown that severe ESD can surpass these requirements. Medistim has therefore further issued updated instructions

for use which clarify the importance of routinely performing the probe and system functionality test before use to ensure that they function properly.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

The MiraQ cardiac transit time flowmetry and high-frequency ultrasound system is intended for people with coronary artery disease who are having coronary artery bypass graft surgery. High blood pressure, high cholesterol, high levels of lipoprotein(a), smoking, physical inactivity, diabetes and being overweight increase the risk of developing coronary heart disease. Older people, people who are male and people of South Asian family origin are also more likely to develop coronary heart disease. Age, disability, sex and race are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Four studies are summarised in this briefing, which include a total of 1,134 people.

All studies are single-arm studies without a comparator. The evidence consists of 1 multicentre observational registry (Taggart et al. 2020), which has 1 secondary analysis from this data (Rosenfeld et al. 2021a), 1 prospective study (Wendt et al. 2019) and 1 retrospective observational study (Kim et al. 2020).

There is 1 secondary analysis that is not summarised below because it includes people with chronic and end-stage renal disease undergoing coronary artery bypass graft (CABG)

surgery (Rosenfeld et al. 2021b).

The clinical evidence and its strengths and limitations are summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence for the technology is of low to moderate quality. None of the studies have a comparator and there is limited evidence in an NHS setting (1 centre). Some of the evidence is on VeriQ C, which is a previous version of the technology. The evidence suggests that MiraQ cardiac with transit time flowmetry (TTFM) and high-frequency ultrasound (HFUS) may improve the quality and efficacy of the CABG procedure. Comparative evidence on patient outcomes would be beneficial.

Taggart et al. (2020)

Study size, design and location

A multicentre prospective observational registry of 1,016 people diagnosed with multivessel coronary artery disease who were scheduled for isolated coronary artery bypass graft surgery in 7 centres in Europe and North America.

Intervention and comparator

MiraQ cardiac or VeriQ C devices with TTFM and HFUS, no comparator.

Key outcomes

HFUS was used to assess the ascending aorta in 79.3% (806 out of 1,016) of people, the in situ conduits in 65.1% (661 out of 1,016), the coronary targets in 47.5% (483 out of 1,016) and completed grafts in 59.3% (602 out of 1,016). People who had off-pump surgery had HFUS more frequently (88.3%) compared with people who had on-pump surgery (73.5%). The primary outcome of the study was any change in planned surgical procedure as a result of imaging with TTFM or HFUS, or from visual assessment. A surgical change was made in 256 people. Of these, in 77% (197 out of 256) this was a result of TTFM or HFUS. Of these, surgical changes were made to the aorta in 74 of 80 people (92.5%), to in situ conduits in 10 of 18 people (55.6%), to the proposed coronary target in 73 of 109 people

(67.0%) and to grafts in 51 of 79 people (64.6%). In-hospital adverse event rates were 0.3% for myocardial infarction, 0.6% for mortality and 1.0% for cerebral events.

Strengths and limitations

The study suggests that TTFM and HFUS may improve the quality, safety and efficacy of CABG procedures. One of the centres was based in the UK. The main author has received research funding, speaking and travelling fees from the company. Seven out of the other 9 authors received travelling support or speaker fees from the company. A limitation of the study is that the outcomes were limited to in-hospital reporting and no further follow up was done.

Rosenfeld et al. (2021)

Study size, design and location

A retrospective review of the REQUEST registry of 1,016 people diagnosed with multivessel coronary artery disease who were scheduled for isolated coronary artery bypass graft surgery in 7 centres in Europe and North America.

Intervention and comparator

MiraQ cardiac or VeriQ C devices with TTFM and HFUS, no comparator.

Key outcomes

This study focused on 3 sub-analyses, comparing on-pump (ONCAB, n=402) with off-pump procedures (OPCAB, n=614), arterial versus venous grafts, and grafts to different territories. There were more surgical changes to the ascending aorta in OPCAB (14.7%) compared with ONCAB (3.4%) procedures (odds ratio [OR] 4.03; 95% confidence interval [CI] 2.32 to 7.20). Strategy changes for in situ conduits occurred less in OPCAB (0.2%) versus ONCAB (2.8%) procedures (OR 0.09; 95% CI 0.01 to 0.56). Changes to coronary targets did not differ between groups (10.4% versus 10.9%; OR 0.95; 95% CI 0.62 to 1.46). However, when comparing only people that underwent HFUS scanning, there were more target location changes in OPCAB (28.6%) versus ONCAB (19.9%) procedures (OR 1.63; 95% CI 1.02 to 2.62). In all study participants, revisions were more common for arterial versus venous grafts (4.7% versus 2.4%; OR 2.05; 95% CI 1.29 to 3.37), and inferior versus anterior (5.1% versus 2.9%; OR 1.77; 95% CI 1.08 to 2.89) and lateral (5.1% versus 2.8%; OR

1.83; 95% CI 1.04 to 3.27) territory grafts.

Strengths and limitations

This study is a secondary analysis of Taggart et al. (2020). It suggests that compared with ONCAB, OPCAB procedures resulted in 4 times more changes related to the ascending aorta. An additional limitation to those mentioned above is that the study did not compare CABG procedures with or without the MiraQ cardiac TTFM and HFUS system because of the nature of the study.

Wendt et al. (2019)

Study size, design and location

A prospective study of 65 people undergoing CABG surgery in Germany.

Intervention and comparator

MiraQ cardiac with TTFM and HFUS, no comparator.

Key outcomes

A surgical strategy change, based on imaging, was done in 10 procedures (15%). Changes related to the cannulation site (n=3), the target opening site (n=2) and the clamping site (n=1). In 3 cases, imaging was used to identify the left anterior descending artery, and in 1 case the imaging confirmed a calcified vessel and a procedure was done to treat the calcification. In 1 case, the graft was revised. Thirty-day mortality was 0% and no stroke was observed.

Strengths and limitations

This study suggests that MiraQ TTFM and HFUS was helpful in evaluating the clamping or cannulation site, the potential opening site of the vessel or the completed anastomosis. A limitation is that the main aim of the study was to evaluate MiraQ TTFM and HFUS in relation to postoperative troponin-I release.

Kim et al. (2020)

Study size, design and location

A retrospective observational study of 53 people undergoing CABG in Korea.

Intervention and comparator

VeriQ C system, no comparator.

Key outcomes

In total, the quality of 141 distal anastomoses was evaluated, of which 123 with normal TTFM results also had good ultrasound findings. Abnormal TTFM findings, including low flow or high pulsatility index, were found in 18 distal anastomoses. The epicardial ultrasound identified that only 3 of these needed revisions. Revisions were not done for the other 15 distal anastomoses and at 1 year after surgery, all 15 of these were patent. The abnormal TTFM results were false positives for 15 of 18 distal anastomoses (83.3%). Epicardial ultrasound was also used to evaluate 32 target epicardial arteries in 30 people to identify the appropriate anastomosis sites. For 5 anastomoses, the target vessels were changed to adjacent vessels based on the ultrasound findings. The early and 1-year overall graft patency rates were 100% (141 anastomoses) and 96.1% (122 of 127 anastomoses), respectively. The early mortality rate was 1.9% (1 of 53 people). Overall, postoperative complications included new-onset atrial fibrillation (n=13; 24.5%), respiratory complications (n=3; 5.7%), low cardiac output syndrome (n=2; 3.8%), and acute kidney injury (n=2; 3.8%).

Strengths and limitations

This study suggests that epicardial ultrasound scanning may be beneficial during CABG surgery to confirm the quality of the surgery and potentially reduce additional procedures. A limitation is that the procedures were done by 1 surgeon.

Sustainability

The company claims the technology will reduce the use of single-use equipment related to the surgical procedure by reducing the need for repeat vascularisation (repeat CABG or

percutaneous coronary intervention [PCI]) and the ionising radiation connected to PCI. Both the TTFM and HFUS probes can be used on multiple patients after cleaning and sterilisation. There is no published evidence to support these claims.

Recent and ongoing studies

Flow distribution in arterial composite grafts in patients with coronary heart disease undergoing coronary artery bypass grafting. ACTRN12622000774729. Status: not yet recruiting. Indication: coronary heart disease leading to coronary artery bypass grafting. Devices: MiraQ TTFM and HFUS. Estimated completion date: not reported. Country: Czech Republic.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Two out of 3 experts were familiar with or had used this technology before.

Level of innovation

Two clinical experts commented that the technology has been around for some time, about 20 years. One expert said that other modalities offer the same information but at no extra cost and 1 expert said that MiraQ cardiac is the most user-friendly form that this technology has been presented in. The other expert said that MiraQ cardiac is a useful tool for quality control of anastomotic issues. Two experts described the standard care used in clinical practice, which includes assessment of graft adequacy and flow by: changes in electrocardiogram measurements and haemodynamic parameters, infusing cardioplegia through a conduit during the procedure and palpation of the conduit. Two of the clinical experts stated that the technology would be used in addition to standard care and 1 said that it has the potential to replace standard care.

Potential patient impact

Two experts said that the primary benefit of the technology for patients is providing

surgeons with detailed objective information about the graft condition and graft flow. This information can be used to make necessary changes to improve blood flow in the graft and potentially reduce long-term graft failure. One expert also highlighted the ability of the technology to detect the position of deep lying arteries, which prevents the surgeon from making unnecessary dissections during the procedure. This may reduce the risk of bleeding and intraoperative complications. Based on this aspect of detection, 1 expert said that the technology is most appropriate for use in people with known peripheral vascular disease and another expert said that it would provide more benefit in people with calcified vessels or small vessels with a high syntax score.

Potential system impact

One expert said that the technology has the potential to standardise the methods used in practice, which are currently subjective and not evidence-based. This expert added that the potential to reduce future cardiac events would mean fewer hospital visits, which would free up resource. All of the experts agreed that the technology will initially cost significantly more than standard care. This is because of the cost of purchasing the technology and disposables, training theatre nursing staff and surgeons, and the extra time required to perform flow measurements and ultrasound assessment. One expert felt that the long-term cost impact would be equal to or less than standard care.

General comments

All 3 experts agreed that the technology would not require any specific changes to facilities and infrastructure, though 2 experts noted that storage space within the operating theatre would be needed. They also agreed that training would be required to achieve competency with the device. One of the experts highlighted that the technology does not automatically record blood pressure during the flow measurement and that this would be useful for retrospective analyses of outcomes. They also said that a small portion of the left internal mammary artery must be prepared for placing the flow probe around the vessel. If this step is not done before the procedure and instead done at the end, this could cause damage to the mammary artery and cause bleeding. All 3 experts suggested that larger studies are needed to determine both the clinical and cost effectiveness of the technology, including in different patient groups. Two experts said that the technology would be needed for all coronary artery bypass graft (CABG) procedures done in the NHS, which is approximately 15,000 a year.

Expert commentators

The following clinicians contributed to this briefing:

- Dr James Barnard, consultant cardiac surgeon at Wythenshawe Hospital Manchester University NHS Foundation Trust. Did not declare any interests.
- Dr Vipin Zamvar, consultant cardiothoracic surgeon at Royal Infirmary of Edinburgh. Did not declare any interests.
- Professor Thanos Athanasiou, professor of cardiac surgery at Imperial College London NHS Trust. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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